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103D CONGRESS
1ST SESSION

S. 124

To establish a temporary program under which parenteral diacetylmorphine will be made available through qualified pharmacies for the relief of intractable pain due to cancer, and for other purposes.

IN THE SENATE OF THE UNITED STATES

JANUARY 21 (legislative day, JANUARY 5), 1993

Mr. INOUYE introduced the following bill; which was read twice and referred to the Committee on Labor and Human Resources

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A BILL

To establish a temporary program under which parenteral diacetylmorphine will be made available through qualified pharmacies for the relief of intractable pain due to cancer, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Compassionate Pain Relief Act".

SEC. 2. FINDINGS.

Congress finds that—

(1) cancer is a progressive, degenerative, and often painful disease that afflicts one out of every four persons in the United States and is the second leading cause of death;

(2) in the progression of terminal cancer, a significant number of patients experience levels of intense and intractable pain that cannot be effectively treated by presently available medication;

(3) the effect of such pain often leads to a severe deterioration in the quality of life of the patient and heartbreak for the family of the patient;

(4) the therapeutic use of parenteral diacetylmorphine is not permitted in the United States but extensive clinical research has demonstrated that the drug is a potent, highly soluble painkilling drug when properly formulated and administered under the supervision of a physician;

(5) it is in the public interest to make parenteral diacetylmorphine available to patients through controlled channels as a drug for the relief of intractable pain due to terminal cancer;

(6) diacetylmorphine is successfully used in Great Britain and other countries for relief of pain due to cancer;

(7) the availability of parenteral diacetylmorphine for the limited purposes of controlling intractable pain due to terminal cancer will not adversely affect the abuse of illicit drugs or increase the incidence of pharmacy thefts;

(8) the availability of parenteral diacetylmorphine will enhance the ability of physicians to effectively treat and control intractable pain due to terminal cancer; and

(9) it is appropriate for the Federal Government to establish a temporary program to permit the use of pharmaceutical dosage forms of parenteral diacetylmorphine for the control of intractable pain due to terminal cancer.

SEC. 3. PARENTERAL DIACETYLMORPHINE PROGRAM.

Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following new part:

"PART N—COMPASSIONATE PAIN RELIEF

"SEC. 399G. PARENTERAL DIACETYLMORPHINE.

"(a) REGULATIONS.—

"(1) IN GENERAL.—Not later than three months after the date of the enactment of this part, the Secretary shall issue regulations establishing a program (referred to in this section as the 'pro-

gram') under which parenteral diacetylmorphine may be dispensed from pharmacies for the relief of intractable pain due to terminal cancer.

"(2) TERMINAL CANCER.—For purposes of this section, an individual shall be considered to have terminal cancer if there is histologic evidence of a malignancy in the individual and the cancer of the individual is generally recognized as a cancer with a high and predictable mortality.

"(b) MANUFACTURING.—Regulations established under this section shall provide that manufacturers of parenteral diacetylmorphine for dispensing under the program shall use adequate methods of, and adequate facilities and controls for, the manufacturing, processing, and packing of such drug to preserve the identity, strength, quality, and purity of the drug.

"(c) AVAILABILITY TO PHARMACIES.—

"(1) REQUIREMENTS.—Regulations established under this section shall require that parenteral diacetylmorphine be made available only to pharmacies that—

"(A) are hospital pharmacies or such other pharmacies as the regulations specify;

"(B) are registered under section 302 of the Controlled Substances Act (21 U.S.C. 822);

"(C) meet such qualifications as the regulations specify; and

"(D) submit an application in accordance with paragraph (2).

"(2) APPLICATION.—An application for parenteral diacetylmorphine shall—

"(A) be in such form and submitted in such manner as the Secretary may prescribe; and

"(B) contain assurances satisfactory to the Secretary that—

"(i) the applicant will comply with such special requirements as the Secretary may prescribe respecting the storage and dispensing of parenteral diacetylmorphine; and

"(ii) parenteral diacetylmorphine provided under the application will be dispensed through the applicant upon the written prescription of a physician registered under section 302 of the Controlled Substances Act (21 U.S.C. 822) to dispense controlled substances in schedule II of such Act (21 U.S.C. 812(2)).

"(3) INTENT OF CONGRESS.—It is the intent of Congress that—

"(A) the Secretary shall primarily utilize hospital pharmacies for the dispensing of parenteral diacetylmorphine under the program; and

"(B) the Secretary may distribute parenteral diacetylmorphine through pharmacies other than hospital pharmacies in cases in which humanitarian concerns necessitate the provision of parenteral diacetylmorphine, a significant need is shown for such provision, and adequate protection is available against the diversion of parenteral diacetylmorphine.

"(d) ILLICIT DIVERSION.—Regulations established by the Secretary under this section shall be designed to protect against the diversion into illicit channels of parenteral diacetylmorphine distributed under the program.

"(e) PRESCRIPTION BY PHYSICIANS.—Regulations established under this section shall—

"(1) require that parenteral diacetylmorphine be dispensed only to an individual in accordance with the written prescription of a physician;

"(2) provide that a physician registered under section 302 of the Controlled Substances Act (21 U.S.C. 822) may prescribe parenteral

diacetylmorphine for individuals for the relief of intractable pain due to terminal cancer;

"(3) provide that any such prescription shall be in writing; and

"(4) specify such other criteria for the prescription as the Secretary may determine to be appropriate.

"(f) FEDERAL FOOD, DRUG, AND COSMETIC ACT.—The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) and titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970 (21 U.S.C. 801 et seq. and 951 et seq.) shall not apply with respect to—

"(1) the importing of opium;

"(2) the manufacture of parenteral diacetylmorphine; and

"(3) the distribution and dispensing of parenteral diacetylmorphine,

in accordance with the program.

"(g) REPORTS.—

"(1) BY THE SECRETARY.—

"(A) IMPLEMENTATION AND ACTIVITIES.—

"(i) IMPLEMENTATION.—Not later than 2 months after the date of the enactment of this part and every third month

thereafter until the program is established under subsection (a), the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Committee on Labor and Human Resources of the Senate a report containing information on the activities undertaken to implement the program.

"(ii) ACTIVITIES.—Not later than 1 year after the date the program is established under subsection (a) and annually thereafter until the program is terminated under subsection (h), the Secretary shall prepare and submit to the committees described in clause (i) a report containing information on the activities under the program during the period for which the report is submitted.

"(B) PAIN MANAGEMENT.—Not later than 6 months after the date of the enactment of this part, the Secretary shall prepare and submit to the Committee on Energy and Commerce of the House of Representatives and the Com-

mittee on Labor and Human Resources of the Senate a report that—

"(i) describes the extent of research activities on the management of pain that have received funds through the National Institutes of Health;

"(ii) describes the ways in which the Federal Government supports the training of health personnel in pain management; and

"(iii) contains recommendations for expanding and improving the training of health personnel in pain management.

"(2) BY THE COMPTROLLER GENERAL.—Not later than 56 months after the date on which the program is established under subsection (a), the Comptroller General of the United States shall prepare and submit to the committees referred to in paragraph (1)(A)(i) a report containing information on the activities conducted under the program during such 56-month period.

"(h) TERMINATION AND MODIFICATION.—

"(1) IN GENERAL.—The Secretary may at any time later than 6 months after the date on which the program is established under subsection (a), modify

the regulations required by subsection (a) or terminate the program if in the judgment of the Secretary the program is no longer needed or if modifications or termination are needed to prevent substantial diversion of the diacetylmorphine.

"(2) FINAL TERMINATION.—The program shall terminate 60 months after the date the program is established under subsection (a).".

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